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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,607	04/21/2004	Carl M. Mendel	BBC-128/1	5201

34213 7590 04/27/2006

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,607	MENDEL ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-13* is/are rejected.

7)☒ Claim(s) *7,9,12 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 3-13 are presented for examination.

Applicant's petition under 37 C.F.R. 1.137(b) to revive the present application from unintentional abandonment as set forth in the papers filed March 23, 2006 was granted pursuant to the notice of petition decision dated April 13, 2006.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Pursuant to the petition to revive the present application from unintentional abandonment, the holding of abandonment for failure to timely respond has been vacated.

Applicant's submission of the amendment filed March 23, 2006 has been received and entered into the present application. Claims 1 and 3-13 remain pending and are herein examined on the merits.

Applicant's request for the status of the rejection of present claims 1 and 3-4 under 35 U.S.C. 102(a) over Mueller (U.S. Patent No. 6,323,242; 2001) has been noted. In view of the amendments to the claims, the reference to Mueller is no longer applicable to the present claims and has hereby been **withdrawn**.

In view of the acceptable nature of the Terminal Disclaimer filed March 23, 2006, the rejection of claims 1 and 3-13 under the judicially created doctrine of obviousness-type double patenting over claims 1-13 of U.S. Patent No. 6,376,553 has been hereby **withdrawn**.

Objections to the Claims

Claim 7 is objected to under 37 C.F.R. 1.75 as being a substantial duplicate of present claim 12. Claim 9 is also objected to under 37 C.F.R. 1.75 as being a substantial duplicate of present claim 13. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In the instant case, claim 7 is drawn to a method of treating neuropathic pain comprising administering to a human in need thereof a therapeutically effective amount of (+)-1-[1-(4-chlorophenyl)cyclobutyl]-3-methylbutylamine, which is identical to the subject matter of the method encompassed by present claim 12. In addition, claim 9 is drawn to a method of treating neuropathic pain comprising administering to a human in need thereof a therapeutically effective amount of (+)-N-{1-[1-(4-chlorophenyl)cyclobutyl]-3-methylbutyl}-N-N-dimethylamine, which is identical to the subject matter of the method encompassed by present claim 13.

Applicant may wish to consider canceling or amending claims 12 and 13, since they are drawn to same subject matter already claimed by present claims 7 and 9.

Objection to the Title

The title of the invention is not commensurate in scope with the claimed subject matter. A new title is required that is clearly indicative of the invention to which the claims are directed.

Applicant may wish to consider amending the title to the following: ---TREATMENT OF NEUROPATHIC PAIN---.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Non-Provisional Rejection

Claims 1 and 3-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,803,387.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the patent and those of the present application are not considered to be patentably distinct from each other because the patented claims clearly anticipate the present claims. The patented claims clearly provide for the

treatment of neuropathic pain as it results from shingles and nerve injury comprising administering to a human in need thereof a therapeutically effective amount of a compound of formula I, which is identical to the genus of compounds presently claimed, wherein the compound is in conjunction with a pharmaceutically acceptable diluent or carrier. While the patented claims are not drawn specifically to neuropathic pain in general, it remains that the claims are ultimately drawn to the same therapeutic objective, regardless of the recitation of the origin of the condition and, thus, anticipate claims to the treatment of the same disorder of any etiology. Such a situation is analogous to a genus-species relationship. The recitation of a "species", in this case, neuropathic pain associated with shingles and nerve injury, will always anticipate the "genus", in this case, neuropathic pain in general (i.e., of any etiology). Please reference MPEP §2131.02 for a discussion of genus-species situations and also *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960) and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

Accordingly, rejection of present claims 1 and 3-13 is deemed proper over claims 1-12 of U.S. Patent No. 6,803,387 as claiming obvious and unpatentable variants thereof.

Provisional Rejection

Claims 1 and 3-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-13 of copending U.S. Patent Application No. 10/979,596.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the

reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the copending claims and those of the present application are not considered to be patentably distinct from each other because the copending claims clearly anticipate the present claims. The copending claims clearly provide for the treatment of neuropathic pain as it results from diabetes and varied peripheral neuropathies comprising administering to a human in need thereof a therapeutically effective amount of a compound of formula I, which is identical to the genus of compounds presently claimed, wherein the compound is in conjunction with a pharmaceutically acceptable diluent or carrier. While the copending claims are not drawn specifically to neuropathic pain in general, it remains that the claims are ultimately drawn to the same therapeutic objective, regardless of the recitation of the origin of the condition and, thus, anticipate claims to the treatment of the same disorder of any etiology. Such a situation is analogous to a genus-species relationship. The recitation of a "species", in this case, neuropathic pain associated with shingles and nerve injury, will always anticipate the "genus", in this case, neuropathic pain in general (i.e., of any etiology). Please reference MPEP §2131.02 for a discussion of genus-species situations and also *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960) and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

Furthermore, it is noted that the ultimate therapeutic objective of both the copending claims and the present claims is identical (i.e., neuropathic pain). Though the copending claims are drawn to the treatment of neuropathic pain as it results from diabetes and varied peripheral neuropathies, it remains that what is being treated as the objective of executing the method is the

treatment of the neuropathic pain, not the treatment of diabetes or the varied peripheral neuropathies. As a result, the origin of the neuropathic pain does not limit the methods and, therefore, the subject matter of the present claims and that of the copending claims does not differ from one another.

Accordingly, rejection of present claims 1 and 3-13 is deemed proper over claims 2-13 of copending U.S. Patent Application No. 10/979,596 as claiming obvious and unpatentable variants thereof.

Subject Matter Not Taught or Fairly Suggested by the Prior Art

In light of the fact that U.S. Provisional Patent Application No. 60/125,113, to which the present application claims priority under 35 U.S.C. 119(e), fully discloses the use of the presently claimed genus of compounds for the treatment of neuropathic pain, the present claims are afforded the effective filing date of this provisional application (March 19, 1999).

Applicant is notified that a comprehensive search and examination of the prior art determined that the art at the time of the instant invention did not otherwise teach, disclose or fairly suggest the use of the presently claimed genus of compounds for the treatment of neuropathic pain prior to the filing of U.S. Provisional Patent Application No. 60/125,113, filed March 19, 1999, of which the present application claims benefit under 35 U.S.C. 119(e).

Should the claims be amended such that they are in condition for allowance, an updated search of the prior art will be made and any newly discovered references will be applied. However, it appears at present that the presently claimed subject matter is free of the art.

Conclusion

Rejection of claims 1 and 3-13 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

April 25, 2006

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